REMARKS

Claims 9-12 and 20-44 are pending in the application. Claims 9-12 and 20-30 are presently withdrawn in view of a prior imposed restriction requirement. Claims 31-44 stand rejected.

The Examiner has rejected claims 31-37 under 35 U.S.C. § 103(a) as being unpatentable over Drug Launches (6 June 1998) ("Drug Launches"). The Examiner contends that Drug Launches teaches chlorohexidine (biguanide compound) that is commercially available in the liquid formulation of 150 ml for the stimulation of hair growth and prevention of hair loss, but concedes that Drug Launches does not expressly teach administering to the mammal the active agent in a manner such that it reaches an affected area of the pilosebaceous apparatus.

The Examiner contends it would have been obvious to one of ordinary skill in the art to employ the chlorohexidine formulation taught by Drug Launches in a mammal for the treatment of alopecia because the chlorohexidine formulation is commercially available for the stimulation of hair growth.

The Examiner has also rejected claims 38-44 under 35 U.S.C. § 103(a) as being unpatenable over Drug Launches (as applied above) and further in view of U.S. Patent No. 6,075,005 of Lurie. The Examiner contends that while Drug Launches does not teach the combination of chlorohexidine with STI, ARB, or an activity enhancing agent, Lurie teaches an anti-androgenic agent such finasteride, spironolactone, flutamide, or RU 58841 as being useful for the treatment of hair growth or alopecia. Thus, the Examiner concludes it would have been obvious to one of skill in the art to combine STI, ARB, with the biguanide compound taught by Drug Launches because all components are well known individually for treating alopecia.

The applicants traverse the rejection.

In order to render a claimed invention obvious, the Examiner must establish that the reference or combination of references teaches or suggests all elements of the invention, that a person of skill in the art would have been motivated to make the modification or combination of the reference, and that he or she would have had a reasonable expectation that the combination or modification would be successful. The Examiner has failed to meet all elements of this test in

the instance of the § 103(a) rejection based upon Drug Launches taken alone and in the instance of the § 103(a) rejection based upon Drug Launches combined with Lurie.

First, the Drug Launches reference teaches a formulation containing seven active ingredients, one of which is chlorohexidine gluconate, which is considered in the art to belong to the biguanide class of materials. However, as is also known in the art, chlorohexidine gluconate is not an insulin sensitivity increasing substance. In contrast, the invention is a method of treating alopecia that comprises administering to the mammal an insulin sensitivity increasing substance ("ISIS") in an amount effective to treat the alopecia in the mammal in a manner so as to reach the effected area of a pilosebaceous apparatus. The ISIS may be a biguanide compound, but all ISIS are not biguanides nor are all biguanide compounds ISIS.

In addition, a person of skill in the art would not have been motivated to make the combination proposed by the Examiner. The Lurie reference is directed to hair growth compositions containing relaxin or a relaxin analog and an anti-androgenic agent. Lurie states that it is the combination of relaxin and relaxin antigens with anti-androgenic agents that is useful in the prevention and treatment of androgenic alopecia and related conditions. Thus, a person of skill in the art would not have been motivated to remove relaxin from the anti-androgenic agents, and substitute instead an ISIS of the present invention, for elimination of the relaxin from the formulation would, according to Lurie, render the formulation less effective. Moreover, there is no indication, suggestion or motivation in either Lurie or Drug Launches that such combination could be successful. Indeed, because the Lurie composition relies upon a synergistic effect of relaxin and the anti-androgenic agents, it impliedly teaches against removal or substitution of the relaxin component.

Thus, for at least these reasons, it is submitted that claims 31-44 are fully patentable over all of the cited references. Accordingly, it is requested that the Examiner reconsider and allow claims 31-44 at the earliest opportunity.

Respectfully submitted,

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